Facsimile Transmittal Sheet

To: EXAMINER SHEIKH

Location: USPTO

FAX Number: 703, 746-9256 Number of Pages

Date: 6/11/03 Including Cover Sheet: 4

From: ALAN RUBIN

Location: WILMINGTON, DELAWARE

Telephone No.: 302, 478-0838

NOTES:

Thanks for agreeing to review the enclosed draft claims on an informal basis – your cooperation is much appreciated.

I look forward to your comments/suggestions regarding the status of the application.

Alan Rubin

APPLICANT: RUBIN, ALAN A.

APPLICATION No: 08/835,482 ART UNIT: 1615

FILED: APRIL 8, 1997 EXAMINER: SHEIKH

DRAFT CLAIMS

1.A pharmaceutical bilayer tablet, which provides rapid and sustained symptomatic relief in Parkinson's disease, avoiding delay in therapeutic onset of action following administration of a formulation comprising an immediate release layer of 10-25 mg carbidopa and 50-200mg levodopa and a sustained release layer of 25-75 mg carbidopa and 100-400 mg levodopa.

11. A method according to claim 1, the bilayer tablet comprising a sustained release core layer of carbidopa-levodopa overcoated by an immediate release layer of carbidopa-levodopa.

12. The pharmaceutical composition of claim 11 wherein at least one sustained release layer of carbidopa-levodopa is separated from at least one immediate release layer of carbidopa-levodopa by an excipient layer which is drug-free and does not necessarily contain rate-controlling polymers.

DRAFT CLAIMS (cont)

17. A method according to claim 11, wherein said method avoids significant onset delay in effecting such treatment said immediate release layer providing rapid onset of anti-Parkinson activity and said sustained release layer providing sustained anti-Parkinson activity.

18. Delete.....redundant.

21. A method for treating Parkinson's disease in a patient having need of such treatment comprising orally administering at least one bilayer tablet to said patient, said tablet having a sustained release core layer consisting essentially of carbidopa, levodopa, methocel, microcrystalline cellulose, croscarmellose sodium, silicon dioxide and magnesium stearate, and an immediate release outer layer over said sustained release core layer, said immediate release layer consisting essentially of carbidopa, levodopa, microcrystalline cellulose, croscarmellose sodium, silicon dioxide and magnesium stearate.

22. A method according to claim 21, wherein said immediate release outer layer contains 12.5 mg carbidopa, 50 mg levodopa, 123.5 mg microcrystalline

DRAFT CLAIMS (cont)

cellulose, 2.0 mg silicon dioxide and 10 mg magnesium stearate, the mg being mg/tablet.

23. A method according to claim 21, wherein said sustained release core layer contains 37.5 mg carbidopa, 150 mg levodopa, 80 mg methocel, 53.5 mg microcrystalline cellulose, 2.0 mg silicon dioxide and 2.0 mg magnesium stearate, the mg being mg/tablet.